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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,207	03/25/2005	Motonori Kidokoro	268422US0PCT	2014
22850 7590 01/02/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER PALENIK, JEFFREY T	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 01/02/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/529,207

Applicant(s)

KIDOKORO ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 25 Mar 2005 & 1 June 2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-12 are presented for consideration. However, dependent claims 8-12 are withdrawn from further consideration at this time (see Claim Objections).

Therefore, claims 1-7 are presented and represent all claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/JP03/12408, filed 29 September 2003. Applicant claims priority to Japanese Foreign Application No. 2002-286286, filed 30 September 2002. Examiner finds that Applicant's filing meets the priority requirements and determines the earliest effective U.S. filing date to be 30 September 2002.

Information Disclosure Statement

Two Information Disclosure Statements filed on 25 March 2005 and 1 June 2005 are acknowledged and have been reviewed.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 8-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8-12 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase “substantially comprising” because this phrase is confusing and misleading in terms of defining the metes and bounds of the components included within the claimed composition. The broadest reasonable interpretation of the term “substantially”, absent any special definition in the instant specification, is interpreted to encompass a more narrow inclusion of elements, opposite that which is implied by the term “comprising”. It is suggested that this phrase be amended to recite “...comprising...”.

The recitation “wherein the total content of the light anhydrous silicic acid and the microcrystalline cellulose amounts to a quantity that yields an adsorptivity of 0.6 or

higher” in claims 2 and 3 lacks clarity. The required “total content” of said constituents is indefinite. It is unclear what amounts of the aforementioned components are required to elicit the claimed adsorptivity result.

The recited weight ratios of the instant claims 6 and 7 lack clarity. As in the case of claim 6, it is unclear, if the cited “1 to 6” relationship between the light anhydrous silicic acid and microcrystalline cellulose is to be interpreted as 1:6 or if it is to be interpreted as a range of 1:1 to 6:1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Murakami et al. (WO 98/02185).

Murakami et al. teaches a compression-molded material comprising an excipient (claim 1), further comprising additives such as diluents, which can be light anhydrous silicic acid (col. 7, lines 13-24) and further comprising an active ingredient such as vitamins (claims 12 and 13), which can be pantethine (col. 5, line 67). Claim 10 further teaches that the excipient used may be microcrystalline cellulose. Methods 2 and 3 (col. 8, lines 6-24) teach dry and wet granulation-tabletting methods, respectively, wherein each of the aforementioned ingredients is incorporated into a compressed tablet form and then crushed to form particulate material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakami et al. (WO 98/02185).

Murakami et al. teaches a compression-molded material, as described above. However, Murakami does not teach the specific adsorptivity values, ratios or ranges of the composition of the instant claims 2-7. Murakami does provide that “[n]o limitation is imposed on the pharmaceutical active ingredients which may be used in the present invention, and they may be added in accordance with intended uses” (col. 5, line 54-58). Table 15 of Example 13 provides an embodiment whereby the combination of the diluent (i.e. D-mannitol) and the excipient (i.e. microcrystalline cellulose) is present in a ratio of

about 0.6:1 with the active ingredient (i.e. Cimetidine). Table 15 also demonstrates a 1:2.5 ratio of the diluent to the excipient within the composition. Since the amount of each ingredient of the granulated composition is adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal type and amount of active ingredient and diluent to add to the excipient composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these ingredient amounts would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone


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number for the organization where this application or proceeding is assigned is 571-270-2966.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik
Patent Examiner


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